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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Aristo Vojdani ) Group Art Unit 1645  
App. No. : 10/007,768 )  
Filed : November 8, 2001 )  
For : SALIVA IMMUNOASSAY FOR DETECTION OF )  
EXPOSURE TO INFECTIOUS AGENTS )  
Examiner : Unknown )

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Dear Sir:

Enclosed is form PTO-1449 listing 54 references that are also enclosed. This Information Disclosure Statement is being filed before the receipt of a first Office Action on the merits, and presumably no fee is required in accordance with 37 C.F.R. § 1.97(b)(3). If a first Office Action on the merits was mailed before the mailing date of this Statement, the Commissioner is authorized to charge the fee set forth in 37 C.F.R. § 1.17(p) to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 3-12-02

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FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. IMSCI2.003A	APPLICATION NO. 10/007,768
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EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
	1 Schoenfeld, Y., Serer, Y., Harats, D. "Atherosclerosis as an Infectious, Inflammatory and Autoimmune Disease." <i>Trends in Immunology</i> . 22:293-295 (2001)
	2 Michalek, S.M., McGhee, J.R., Babb, J.L., "Effective Immunity to Dental Caries: Dose-Dependent Studies of Secretory Immunity by Oral Administration of <i>Streptococcus mutans</i> to Rats." <i>Infect Immun</i> 1978; 19:217-224.
	3 Husband, A.M., Gowans, "The Origin and Antigen-Dependent Distribution of IgA-Containing Cells in the Intestine." <i>J Exp. Med</i> 1978; 148:1146-60
	4 Kagnoff, M.F., "Effects of Antigen-Feeding on Intestinal and Systemic Immune Responses. I. Priming of Precursor Cytotoxic T Cells by Antigen Feeding." <i>J Immunol</i> 1978; 120: 395-399.
	5 Mestecky, J., McGhee, J.R., Arnold, R.R., et al., "Selective Induction of an Immune Response in Human External Secretions by Ingestion of Bacterial Antigen." <i>J Clin Invest</i> 61: 731-737, 1978
	6 Cunningham-Rundles, C., Brandeis, W.E., et al., "Bovine Antigens and the Formation of Circulating Immune Complexes in Selective Immunoglobulin A Deficiency." <i>J Clin Invest</i> . 64:272-279, 1979
	7 Brandtzaeg, P., "Transport Models for Secretory IgA and Secretory IgM." <i>Clin Exp. Immunol.</i> 44:221-232, 1981.
	8 Concha, E., Subiza, J.L., et al., "Disorders of Regulatory T Cells in Patients With Selective IgA Deficiency and its Relationship to Associated Autoimmune Phenomena." <i>Clin Exp. Immunol.</i> 49:410-418, 1982.
	9 Bienenstock, J., Befus, A.D., "Some Thoughts on the Biologic Role of Immunoglobulin A." <i>Gastroenterology</i> . 84:178-185, 1983.
	10 Romero-Piffiguer, Vucovich, P.R., and Riera, C.M., "Secretory IgA and Secretory Component in Women Affected by Recidivant Vaginal Candidiasis." <i>Mycopathologia</i> 91:165-170, 1985.
	11 Stone, A.A., Cox, D.S., et al., "Secretory IgA as a Measure of Immunocompetence." <i>J. Human Stress</i> . 13:136-140, 1987.
	12 Epstein, M.M., Baumgarten, A., "The Usefulness of Routine Screening For Salivary Secretory Component." <i>J Allerg Clin Immunol.</i> 88:356-360, 1991.
	13 Listgarten, M.A., "Structure of the Microbial Flora Associated With Periodontal Health and Disease in Man." <i>J. Periodontal</i> (1976) 47:1-18.
	14 Genco, R.J., "Immunoglobulins and Periodontal Disease." <i>J. Periodontal</i> (1970) 41:196-201.
	15 Genco, R.J. Mashimo, P.A., et al., "Antibody-Mediated Effects on the Periodontium." <i>J. Periodontal</i> (1974) 45:330-337.
	16 Ebersole, J.L., "Systemic Humoral Immune Responses in Periodontal Disease." <i>Crit Rev Oral Bio Med</i> (1990) 1:283-331.
	17 Lally, E.T., Baehni, P.C., et al., "Local Immunoglobulin Synthesis in Periodontal Disease." <i>J. Periodont Res</i> (1980) 15:159-164.
	18 Kiyono, H., Ogawa, T., et al., "Immune Mechanisms in Periodontitis: Total and Antigen-Specific IgG and IgA Subclass Antibody-Producing Cells at the Disease Site." <i>Protides Biological Fluids</i> (1989) 36:229-237.
	19 Tew, J.G., Marshall, D.R., et al., "Relationship Between Gingival Crevicular Fluid and Serum Antibody Titers in Young Adults and Generalized and Localized Periodontitis." <i>Infect Immun</i> (1985) 49:487-493.
	20 Schenkein, HA., "The Complement System in Periodontal Diseases." In Genco, R.J., Mergenhagen, S.E., eds. "Hosts-Parasite Interactions in Periodontal Diseases" <i>Washington, D.C. American Society for Microbiology</i> (1982) 299-308.
	21 Niekraash, C.E., Patters, M.R., "Simultaneous Assessment of Complement Components C3, C4, and B and their Cleavage Products in Human Gingival Fluid. II. Longitudinal Changes During Periodontal Therapy." <i>J. Periodont Res</i> (1985) 20:268-275.

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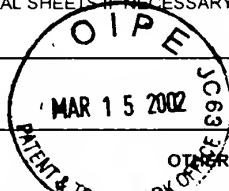
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EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
	22 Califano, J., Schifferle, R.E., et al., "Antibody Reactive With <i>Porphyromonas Gingivalis</i> Serotypes K1-6 in Adult and Generalized Early-Onset Periodontitis." <i>J. Periodont</i> (1999) 70:730-735.
	23 Saito, S., Hayakawa, M., et al., "Opsonophagocytic Effect of Antibody Against Recombinant Conserved 40-kDa Outer Membrane Protein of <i>Porphyromonas Gingivalis</i> ." <i>J. Periodontal</i> (1999) 70:610-617.
	24 Rose, N.R., Herkowitz, A., et al. "Autoimmune Myocarditis: A Paradigm of Post-Infection Autoimmune Disease." <i>Immunology Today</i> 9: 117-120 (1988)
	25 Kroes, I., Lepp, P.W., et al., "Bacterial Diversity Within the Human Subgingival Crevice." <i>Proc Natl Acad Sci USA</i> . 96, 14547-14552 (1999).
	26 Bachmaier, K., Neu, N., et al., " <i>Chlamydia</i> Infections and Heart Disease Linked Through Antigenic Mimicry." <i>Science</i> . 283, 1335-1339 (1999).
	27 Ridker, P.M., Kundsinn, R.B., et al., "Prospective Study of <i>Chlamydia Pneumoniae</i> IgG Seropositivity and Risks of Future Myocardial Infarction." <i>Circulation</i> . 99, 1161-1164 (1999).
	28 Rose, N.R., "Viral Damage or 'Molecular Mimicry'--Placing the Blame in Myocarditis." <i>Nature Medicine</i> 6: 631-632 (2000)
	29 Bachmaier, J., Le, J., et al., "Catching Heart Disease: Antigenic Mimicry and Bacterial Infections." <i>Nature Medicine</i> 6: 841-842 (2000)
	30 Parums, D.V., Brown, D.L., et al., "Serum Antibodies to Oxidized Low-Density Lipoprotein and Ceroid in Chronic Periaortitis." <i>Arch Pathol Lab Med</i> 114:383-387
	31 Salonen, J.T., et al., Autoantibody Against Oxidized LDL and Progression of Carotid Atherosclerosis." <i>Lancet</i> 339:883-887 (1992).
	32 Schoenfeld, Y., et al., "Atherosclerosis as an Infectious, Inflammatory and Autoimmune Disease." <i>Trends in Immunology</i> 22: 293-295 (2001).
	33 Wick, G., Schett, G., et al., "Is Atherosclerosis an Immunologically Mediated Disease?", <i>Immunology Today</i> 16, 27-33 (1995).
	34 Shoenfeld, Y., et al., "Autoantibodies Associated with Atherosclerosis." <i>Ann Med</i> . 32 (Suppl. 1), 37-40 (2000).
	35 Shoenfeld, Y., et al., "Atherosclerosis and Autoimmunity." <i>Elsevier Science</i> (2001) 5-13
	36 McNeil, H.P., et al., "Anti-Phospholipid Antibodies Are Directed Against a Complex Antigen that Includes a Lipid-Binding Inhibitor of Coagulation: $\beta_2$ -Glycoprotein I (Apolipoprotein H)." <i>Proc Natl Acad Sci USA</i> 87:4120-4124 (1990)
	37 Galli, M., et al., "Anticardiolipin Antibodies (ACA) Directed Not to Cardiolipin But to a Plasma Protein Cofactor." <i>Lancet</i> 335:1544-1547 (1990).
	38 Kandiah, D.A., Krilis, S.A., "Immunology and Methods of Detection of Antiphospholipid Antibodies." In <i>The Antiphospholipid Syndrome</i> . R.A. Asherson, R. Cervera, J.C. Piette and Y. Shoenfeld, eds., CRC Press. Boca Raton, FL P.29-48 (1996)
	39 Arvieux, J., et al., "Measurement of Anti-Phospholipid Antibodies by ELISA Using $\beta_2$ -Glycoprotein I as an Antigen." <i>J. Immunol Methods</i> 143:223-229 (1991)
	40 George, J., et al., "Adoptive Transfer of $\beta_2$ -Glycoprotein I--Reactive Lymphocytes Enhances Early Atherosclerosis in LDL Receptor--Deficient Mice." <i>Circulation</i> 102, 1822-1827 (2000)
	41 Sheng, Y., et al., "Anti- $\beta_2$ -Glycoprotein I Autoantibodies From Patients With the 'Antiphospholipid' Syndrome Bind to $\beta_2$ -Glycoprotein I Induces a Significant Increase in Anti- $\beta_2$ -Glycoprotein I Antibody Affinity." <i>J. of Immunology</i> 161: 2038-2043 (1998).
	42 Hegde, U.M., "Platelet Antibodies in Immune Thrombocytopenia." <i>Blood Rev</i> 6:34-42 (1992)

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	43 Hasselaar, P., et al., "Crossreactivity of Antibodies Directed Against Cardiolipin, DNA, Endothelial Cells and Blood Platelets." <i>Thromb Haemo</i> 63: 169-173 (1990)
	44 Karpatkin, S., "Immunologic Thrombocytopenic Purpura in HIV-Seropositive Homosexuals, Narcotic Addicts and Hemophiliacs." <i>Semin Hemat</i> Vol. 25, No. 3 (July) (1988) 219-229
	45 Ratner, L., "Human Immunodeficiency Virus-Associated Autoimmune Thrombocytopenic Purpura: A Review." <i>Am J Med</i> 86: 194-198 (1989)
	46 McWilliams, N.B. Maurer, H.M., "Acute Idiopathic Thrombocytopenic Purpura in Children." <i>Am J Hematol</i> 7:87-96 (1979)
	47 Cordiano, I., et al., "Biotin-Avidin Immobilization of Platelet Glycoproteins (BAIPG): A New Capture Assay For the Detection of Anti-Platelet Antibodies." <i>J Immunol Methods</i> 178 (1995) 121-130.
	48 Theofilopoulos, A.N., et al., "The Raji Cell Radioimmune Assay For Detecting Immune Complexes in Human Sera." <i>J Clin Invest</i> Vol. 57 (January) (1976) 169-182.
	49 Aziz, M., et al., "Evaluation of Cell-Mediated Immunity and Circulating Immune Complexes as Prognostic Indicators in Cancer Patients." <i>Cancer Detection and Prevention</i> , 22(2): 87-99 (1998)
	50 Lizza, F., et al., "Evaluation of a Commercial Serological Kit for Detection of Salivary Immunoglobulin G to <i>Helicobacter pylori</i> : A multicentre Study." <i>Eur J of Gastroenterology &amp; Hepatology</i> , 2000, 12:117-1120
	51 Tuuminen, T., et al., "Development of Enzyme Immunoassays to Detect Salivary IgA to <i>Chlamydia pneumoniae</i> and <i>Mycoplasma pneumoniae</i> ." <i>Scand J Clin Lab Invest</i> 2001; 61:357-362
	52 Lizza, F., et al., "Salivary Immunoglobulin G Assay To Diagnose <i>Helicobacter pylori</i> Infection in Children." <i>J Clin Microbiology</i> , Dec. 1997, Vol. 35, No. 12, pp. 3358-3360
	53 Simor, A.E., et al., "Evaluation of Enzyme Immunoassay For Detection of Salivary Antibody to <i>Helicobacter pylori</i> ." <i>J Clin Microbiology</i> , Mar. 1996 Vol. 34, No. 3 p. 550-553.
	54 Lizza, F., et al., "Salivary Specific IgG is a Sensitive Indicator of the Humoral Immune Response to <i>Helicobacter pylori</i> ." <i>FEMS Immunol Med Microbiol.</i> 10 (1995) 281-284.

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